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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/029,543	12/08/1998	ELIEZER RACHAMAN	P-68712-US	6203

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EXAMINER

PESELEV, ELLI

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/029,543

Applicant(s)

RACHAMAN ET AL.

Examiner

Elli Peselev

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The disclosure is objected to because of the following informalities: It is improper to have Figure 1 as part of the specification on [age 5. All Figures should be presented separately as drawings.

Appropriate correction is required.

Claims 15-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims are drawn to pyradinium derivatives wherein R1 and R2 are alkenyl, aryl, aralkyl, cycloalkyl, cycloalkylalkyl, A is alkylene, alkenylene or alkynylene and Z is dialkylcarbamoyl and Q can be substituted or coupled to a physiologically active acceptable moiety. Said groups are not limited to any number of carbon atoms.

(B) The state of the prior art.

The prior art fails to show pyradinium compounds substituted with the above stated moieties.

(C) The level of one of ordinary skill.

One of ordinary skill in the art would be a Physician with an M.D./PhD.

(D) The level of predictability in the art.

It is well known in the art that even minor changes in the structural formula of a compound can greatly affect its activity. The variables set forth in claim 15 are not limited to any number of carbon atoms. A person having ordinary skill in the art at the time the instant invention was made would not have been able to predict that the claimed compound, wherein, for example R1 is alkenyl having 2 carbon atoms will have the same activity as an alkenyl group having 100 carbon atoms.

(E) The amount of direction provided by the inventor.

The inventor has not provided any direction on how to choose the specific variables which will result in a compound having the desired activity.

(F) The existence of working examples.

No working examples are provided to the various substituents encompassed by the instant claims.

(G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

It would take an undue amount of experimentation to determine which specific alkenyl, aryl, aralkyl, cycloalkyl, cycloalkylalkyl, alkylene, alkynylene, alkynylene, dialkylcarbamaoyl or a physiologically active acceptable moiety will produce the desired compounds since the above cited moieties are not limited to any number of carbons and therefore encompass such a large number of groups. Further, the terminology "a physiologically active acceptable moiety" (claim 15) encompass all active moieties, such

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as heterocyclics, amino acids, steroids, peptides, nucleosides, sugars, etc. Therefore, it would take an undue amount of experimentation to determine which specific moieties will be useful in the claimed invention.

Claims 15, 17 and 32-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "polyphosphorylated sugar" (claim 15) is not disclosed or suggested by the specification as originally filed.

Claims 16, 20, 24, 25 and 35) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 15 for Q representing alditols, ascorbic acid or its derivatives (claims 16, 20, 24 and 25).

Claim 35 is indefinite in that it is directed to the treatment of more than one disease at the same time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200